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(Original Signature of Member)

116TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To prevent wasteful and abusive billing of ancillary services to the Medicare program, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

Ms. SPEIER introduced the following bill; which was referred to the Committee  
on \_\_\_\_\_

\_\_\_\_\_

**A BILL**

To prevent wasteful and abusive billing of ancillary services  
to the Medicare program, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Promoting Integrity  
5       in Medicare Act of 2019” or “PIMA of 2019”.

6       **SEC. 2. FINDINGS; PURPOSES.**

7       (a) FINDINGS.—Congress finds the following:

8               (1) Recent studies by the Government Account-  
9       ability Office (GAO) examining self-referral practices

1 in advanced diagnostic imaging and anatomic pa-  
2 thology determined that financial incentives were the  
3 most likely cause of increases in self-referrals.

4 (2) For advanced diagnostic imaging, GAO  
5 stated that “providers who self-referred made  
6 400,000 more referrals for advanced imaging serv-  
7 ices than they would have if they were not self-refer-  
8 ring”, at a cost of “more than \$100 million” in  
9 2010.

10 (3) For anatomic pathology, GAO found that  
11 “self-referring providers likely referred over 918,000  
12 more anatomic pathology services” than they would  
13 have if they were not self-referring, costing Medicare  
14 approximately \$69,000,000 more in 2010 than if  
15 self-referral was not permitted.

16 (4) For radiation oncology, GAO found that in-  
17 tensity modulated radiation therapy (IMRT) utiliza-  
18 tion among self-referring groups increased by 356  
19 percent, with overall increases in IMRT utilization  
20 rates and spending due entirely to services per-  
21 formed by limited-specialty groups. The GAO con-  
22 cluded that “the higher use of IMRT by self-refer-  
23 ring providers results in higher costs for Medicare  
24 and beneficiaries. To the extent that treatment deci-  
25 sions are driven by providers’ financial interest and

1 not by patient preference, these increased costs are  
2 difficult to justify”.

3 (5) For physical therapy, GAO found that “in  
4 the year a provider began to self-refer, physical ther-  
5 apy service referrals increased at a higher rate rel-  
6 ative to non-self-referring providers of the same spe-  
7 cialty”.

8 (6) Noting the rapid growth of services covered  
9 by the in-office ancillary services (IOAS) exception  
10 and evidence that these services are sometimes fur-  
11 nished inappropriately by referring physicians, the  
12 Medicare Payment Advisory Commission (MedPAC)  
13 stated that physician self-referral of ancillary serv-  
14 ices creates incentives to increase volume under  
15 Medicare’s current fee-for-service payment systems  
16 and the rapid volume growth contributes to Medi-  
17 care’s rising financial burden on taxpayers and bene-  
18 ficiaries.

19 (7) The President’s Fiscal Year 2017 Budget  
20 includes the change to remove the four services: ad-  
21 vanced diagnostic imaging, anatomic pathology, radi-  
22 ation oncology, and physical therapy from the IOAS  
23 exception to the Stark Law and cited the change as  
24 generating a savings score of \$4,980,000,000 over  
25 10 years. The nonpartisan Congressional Budget Of-

1        fice's analysis of the President's Fiscal Year 2017  
2        Budget listed the change as generating a savings of  
3        \$3,300,000,000 over 10 years.

4            (8) According to the Centers for Medicare &  
5        Medicaid Services, a key rationale for the IOAS ex-  
6        ception was to permit physicians to provide ancillary  
7        services in their offices to better inform diagnosis  
8        and treatment decisions at the time of the patient's  
9        initial office visit.

10           (9) It is necessary, therefore, to distinguish be-  
11        tween services and procedures that were intended to  
12        be covered by the IOAS exception, such as routine  
13        clinical laboratory services or simple x-rays that are  
14        provided during the patient's initial office visit, and  
15        other health care services which were clearly not en-  
16        visioned to be covered by that exception because they  
17        cannot be performed or completed during the pa-  
18        tient's initial office visit.

19           (10) According to a 2010 Health Affairs study,  
20        less than 10 percent of CT, MRI, and Nuclear Medi-  
21        cine scans take place on the same day as the initial  
22        patient office visit.

23           (11) According to a 2012 Health Affairs study,  
24        urologists' self-referrals for anatomic pathology serv-  
25        ices of biopsy specimens is linked to increased use

1 and volume billed along with a lower detection of  
2 prostate cancer.

3 (12) According to an October 2011 Laboratory  
4 Economics report, there has been an increase in the  
5 number of anatomic pathology specimen units billed  
6 to the Medicare part B program from 2006 through  
7 2010, specifically for CPT Code 88305, and the rate  
8 of increase billed by physician offices for this service  
9 is accelerating at a far greater pace than the rest of  
10 the provider segments.

11 (13) According to a 2013 American Academy of  
12 Dermatology Pathology Billing paper, arrangements  
13 involving the split of the technical and professional  
14 components of anatomic pathology services among  
15 different providers may endanger patient safety and  
16 undermine quality of care.

17 (14) In November 2012, Bloomberg News re-  
18 leased an investigative report that scrutinized or-  
19 deals faced by California prostate cancer patients  
20 treated by a urology clinic that owns radiation ther-  
21 apy equipment. The report found that physician self-  
22 referral resulted in a detrimental impact on patient  
23 care and drove up health care costs in the Medicare  
24 program. The Wall Street Journal, the Washington  
25 Post, and the Baltimore Sun have also published in-

1       vestigations showing that urology groups owning ra-  
2       diation therapy machines have utilization rates that  
3       rise quickly and are well above national norms for  
4       radiation therapy treatment of prostate cancer.

5           (15) According to a 2010 MedPAC report, only  
6       3 percent of outpatient physical therapy services  
7       were provided on the same day as an office visit,  
8       only 9 percent within 7 days of an office visit, and  
9       only 14 percent within 14 days of an office visit.  
10      These services are not integral to the physician's ini-  
11      tial diagnosis and do not improve patient conven-  
12      ience because patients must return for physical ther-  
13      apy treatments.

14           (16) In an April 2018, European Urology arti-  
15      cle authored by leading urologists about Medicare  
16      beneficiaries with prostate cancer diagnoses, re-  
17      searchers found, "Urologists practicing in single-spe-  
18      cialty groups with an ownership interest in radiation  
19      therapy are more likely to treat men with prostate  
20      cancer, including those with a high risk of noncancer  
21      mortality." This suggests that urologists practicing  
22      in single-specialty groups with an ownership interest  
23      in radiation therapy are more likely to treat, and  
24      even potentially overtreat, patients with IMRT than

1       those affiliated with a multispecialty practice or a  
2       group without an ownership stake.

3           (17) In a January 2019, JAMA Oncology arti-  
4       cle, authors systematically reviewed 18 studies to as-  
5       sess physicians’ response to reimbursement incen-  
6       tives on cancer care delivery across various clinical  
7       settings. Across the studies, the authors consistently  
8       found that “the ability to self-refer for radiation on-  
9       cology services was associated with increased use of  
10      radiation therapy”.

11          (18) Those services intended to be covered  
12      under the IOAS exception are not affected by this  
13      legislation.

14          (19) The exception to the ownership or invest-  
15      ment prohibition for rural providers in the “Stark”  
16      rule is not affected by this legislation.

17      (b) PURPOSES.—The purposes of this Act are the fol-  
18      lowing:

19          (1) Maintain the in-office ancillary services ex-  
20      ception and preserve its original intent by removing  
21      certain complex services from the exception—specifi-  
22      cally, advanced imaging, anatomic pathology, radi-  
23      ation therapy, and physical therapy.

24          (2) Protect patients from misaligned provider  
25      financial incentives.

1           (3) Protect Medicare resources by saving bil-  
2       lions of dollars.

3           (4) Accomplish the purposes described in para-  
4       graphs (1), (2), and (3) in a manner that does not  
5       alter the existing exception to the ownership or in-  
6       vestment prohibition for rural providers.

7   **SEC. 3. LIMITATION ON APPLICATION OF PHYSICIANS’**  
8                   **SERVICES AND IN-OFFICE ANCILLARY SERV-**  
9                   **ICES EXCEPTIONS.**

10       (a) IN GENERAL.—Section 1877(b) of the Social Se-  
11   curity Act (42 U.S.C. 1395nn(b)) is amended—

12           (1) in paragraph (1), by inserting “, other than  
13       specified non-ancillary services,” after “section  
14       1861(q))”; and

15           (2) in paragraph (2), by inserting “, specified  
16       non-ancillary services,” after “(excluding infusion  
17       pumps)”.

18       (b) INCREASE OF CIVIL MONEY PENALTIES.—Sec-  
19   tion 1877(g) of the Social Security Act (42 U.S.C.  
20   1395nn(g)) is amended—

21           (1) in paragraph (3), by inserting “, unless  
22       such bill or claim included a bill or claim for a speci-  
23       fied non-ancillary service, in which case the civil  
24       money penalty shall be not more than \$25,000 for



1 each such service” before the period at the end of  
2 the first sentence; and

3 (2) in paragraph (4), by inserting “(or  
4 \$150,000 if such referrals are for specified non-an-  
5 cillary services)” after “\$100,000”.

6 (c) ENHANCED SCREENING OF CLAIMS.—Section  
7 1877(g) of the Social Security Act (42 U.S.C. 1395nn(g))  
8 is further amended by adding at the end the following new  
9 paragraph:

10 “(7) COMPLIANCE REVIEW FOR SPECIFIED  
11 NON-ANCILLARY SERVICES.—

12 “(A) IN GENERAL.—Not later than 180  
13 days after the date of the enactment of this  
14 paragraph, the Secretary, in consultation with  
15 the Inspector General of the Department of  
16 Health and Human Services, shall review com-  
17 pliance with subsection (a)(1) with respect to  
18 referrals for specified non-ancillary services in  
19 accordance with procedures established by the  
20 Secretary.

21 “(B) FACTORS IN COMPLIANCE REVIEW.—  
22 Such procedures—

23 “(i) shall, for purposes of targeting  
24 types of entities that the Secretary deter-  
25 mines represent a high risk of noncompli-

1           ance with subsection (a)(1) with respect to  
2           such billing for such specified non-ancillary  
3           services, apply different levels of review  
4           based on such type; and

5                   “(ii) may include prepayment reviews,  
6           claims audits, focused medical review, and  
7           computer algorithms designed to identify  
8           payment or billing anomalies.”.

9           (d) DEFINITION OF SPECIFIED NON-ANCILLARY  
10       SERVICES.—Section 1877(h) of the Social Security Act  
11       (42 U.S.C. 1395nn(h)) is amended by adding at the end  
12       the following new paragraphs:

13                   “(8) SPECIFIED NON-ANCILLARY SERVICES.—

14                           “(A) Subject to subparagraph (B), the  
15           term ‘specified non-ancillary service’ means the  
16           following:

17                                   “(i) Anatomic pathology services, as  
18           defined by the Secretary and including the  
19           technical or professional component of the  
20           following:

21   “(I) Surgical pathology.

22   “(II) Cytopathology.

23   “(III) Hematology.

24   “(IV) Blood banking.

1 “(V) Pathology consultation and  
2 clinical laboratory interpretation serv-  
3 ices.

4 “(ii) Radiation therapy services and  
5 supplies, as defined by the Secretary.

6 “(iii) Advanced diagnostic imaging  
7 studies (as defined in section  
8 1834(e)(1)(B)).

9 “(iv) Physical therapy services (as de-  
10 scribed in paragraph (6)(B)).

11 “(v) Any other service that the Sec-  
12 retary has determined is not usually pro-  
13 vided and completed as part of the office  
14 visit to a physician’s office in which the  
15 service is determined to be necessary.

16 “(B) The term ‘specified non-ancillary  
17 service’ does not include the following:

18 “(i) Any service that is furnished—

19 “(I) in an urban area (as defined  
20 in section 1886(d)(2)(D)) to an indi-  
21 vidual who resides in a rural area (as  
22 defined in such section); and

23 “(II) to such individual in its en-  
24 tirety on the same day as the day on  
25 which, with respect to the condition

1 for which the service is furnished, the  
2 initial office visit of the individual for  
3 such condition occurs.

4 “(ii) Any service that is furnished—

5 “(I) by a provider of services or  
6 supplier participating in an account-  
7 able care organization that partici-  
8 pates in the shared savings program  
9 established under section 1899; and

10 “(II) to a Medicare fee-for-serv-  
11 ice beneficiary (as defined in section  
12 1899(h)(3)) assigned to such account-  
13 able care organization.

14 “(iii) Any service that is furnished by  
15 a provider or supplier pursuant to the par-  
16 ticipation of the provider or supplier in a  
17 payment and service delivery model se-  
18 lected under section 1115A(a).

19 “(iv) Any service that is provided by  
20 an integrated multi-specialty group prac-  
21 tice.

22 “(9) INTEGRATED MULTI-SPECIALTY GROUP  
23 PRACTICE.—The term ‘integrated multi-specialty  
24 group practice’ means a group practice, as defined  
25 by the Secretary, that—

1 “(A) consists of at least—

2 “(i) primary care physicians who pro-  
3 vide primary care services (as defined in  
4 section 1842(i)(4)); and

5 “(ii) seven or more different and dis-  
6 tinct physician specialties (not including  
7 subspecialties) which are practiced by phy-  
8 sicians who are board certified in the phy-  
9 sician specialty associated with the services  
10 that they provide;

11 “(B) is governed by a governing body that  
12 has made a determination (and has documented  
13 such determination) that the system is focused  
14 on—

15 “(i) promoting accountability for the  
16 quality, cost, and overall care for individ-  
17 uals entitled to benefits under part A or  
18 enrolled in part B, including by managing  
19 and coordinating care for such individuals;  
20 and

21 “(ii) encouraging investment in infra-  
22 structure and redesigned care processes for  
23 high quality and efficient service delivery  
24 for patients, including individuals described  
25 in clause (i); and

1           “(C) engages in risk-based payment ar-  
2           rangements with government and commercial  
3           payers, including shared savings, bundled pay-  
4           ment arrangements, withholds, and capitated  
5           payment arrangements; and

6           “(D) meets, with respect to the program  
7           under this title, such cost reduction and quality  
8           goals as the Secretary determines appro-  
9           priate.”.

10       (e) CONSTRUCTION.—Nothing in this section (or the  
11       amendments made by this section) shall be construed to  
12       affect the authority of the Secretary of Health and Human  
13       Services to waive under section 1899 of the Social Security  
14       Act (42 U.S.C. 1395jjj) the requirements imposed under  
15       the provisions of this section (or such amendments) or to  
16       affect the authority of the Secretary to implement the pro-  
17       visions under section 1848(q) of such Act (42 U.S.C.  
18       1395w–4(q)) (relating to the eligible professionals Merit-  
19       Based Incentive Payment System under the Medicare pro-  
20       gram) or section 1833(z) of such Act (42 U.S.C. 1395l(z))  
21       (relating to incentive payments for participation in eligible  
22       alternative payment models under such program).

23       (f) EFFECTIVE DATE.—The amendments made by  
24       this section shall apply to items and services furnished on  
25       or after the first day of the first month beginning more

1 than 12 months after the date of the enactment of this  
2 Act.

3 **SEC. 4. CLARIFICATION OF CERTAIN ENTITIES SUBJECT TO**  
4 **STARK RULE AND ANTI-MARKUP RULE.**

5 Section 1877(h) of the Social Security Act (42 U.S.C.  
6 1395nn(h)) is further amended by adding at the end the  
7 following new paragraph:

8 “(10) CLARIFICATION OF CERTAIN ENTITIES  
9 SUBJECT TO ANTI-MARKUP RULE.—In applying this  
10 section, the term ‘entity’ shall include a physician’s  
11 practice when it bills under this title for the tech-  
12 nical component or the professional component of a  
13 specified non-ancillary service, including when such  
14 service is billed in compliance with section  
15 1842(n)(1).”.

16 **SEC. 5. CLARIFICATION OF SUPERVISION OF TECHNICAL**  
17 **COMPONENT OF ANATOMIC PATHOLOGY**  
18 **SERVICES.**

19 Section 1861(s)(17) of the Social Security Act (42  
20 U.S.C. 1395x(s)(17)) is amended—

21 (1) by striking “and” at the end of subpara-  
22 graph (A);

23 (2) by redesignating subparagraph (B) as sub-  
24 paragraph (C); and

1 (3) by inserting after subparagraph (A) the fol-  
2 lowing new subparagraph:

3 “(B) with regard to the provision of the  
4 technical component of anatomic pathology  
5 services, meets the applicable supervision re-  
6 quirements for laboratories certified in the sub-  
7 specialty of histopathology, pursuant to section  
8 353 of the Public Health Service Act; and”.

9 **SEC. 6. EXEMPTION FROM BUDGET NEUTRALITY UNDER**  
10 **PHYSICIAN FEE SCHEDULE.**

11 Section 1848(c)(2)(B)(v) of the Social Security Act  
12 (42 U.S.C. 1395w-4(c)(2)(B)(v)) is amended by adding  
13 at the end the following new subclause:

14 “(XII) CHANGES TO LIMITA-  
15 TIONS ON CERTAIN PHYSICIAN REFER-  
16 RALS.—Effective for fee schedules es-  
17 tablished beginning with 2019, re-  
18 duced expenditures attributable to the  
19 Promoting Integrity in Medicare Act  
20 of 2019.”.